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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,508	06/27/2005	Zeger Debyser	50304/072001	6752

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EXAMINER	
WOLLENBERGER, LOUIS V	
ART UNIT	**PAPER NUMBER**
1635	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,508	DEBYSER ET AL.	
	Examiner	Art Unit	
	Louis V. Wollenberger	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *30-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendments

Applicants' preliminary amendments to the claims, filed 3/28/05 are acknowledged. With entry of the amendment, claims 30–56 are pending and subject to restriction as follows.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 30–37, drawn to a pharmaceutical composition comprising a molecule which comprises a region specifically interacting with protein LEDGF/P75 or a fragment thereof or a nucleic acid encoding said protein or fragment, for the treatment or prevention of viral infections in a mammal. Election of this group requires the further election of a single type of molecule from claim 33 and claims 34–37, as explained below.

Group II, claim(s) 38–43, drawn to a method of treating or preventing viral infections in a mammal, which method comprises administering to said mammal a molecule which comprises a region specifically interacting with LEDGF/P75 or a fragment thereof or a nucleic acid encoding

said LEDGF/P75 or fragment thereof. Election of this group requires the further election of a single type of molecule from claim 39 and claims 40–42, as explained below.

Group III, claim(s) 44–50, drawn to a method of drug discovery comprising the step of exposing a molecule to the protein LEDGF/P75 or a nucleic acid encoding said LEDGF/P75. Election of this group requires the further election of a single method of drug discovery involving either the protein LEDGF/P75 or a nucleic acid encoding said LEDGF/P75, as recited in claims 44, 45, and 46, as explained below44

Group IV, claim(s) 51, drawn to a method for modulating the interaction of LEDGF/P75 with lentiviral integrase, which comprises the use of a molecule comprising a region specifically interacting with said protein LEDGF/P75 or nucleic acids encoding said protein or with fragments, allelic variants, a homologue, a portion or mutations of the protein or nucleic acids. Election of this group requires the further election of a single type of molecule specifically interacting with either 1) the protein LEDGF/P75, 2) the nucleic acid encoding the protein, 3) a fragment, 4) allelic variant, 5) homologue, 6) portion, or 7) mutation of the protein, or 8–12) of the nucleic acid, as explained below.

Group V, claim(s) 52 and 53, drawn to a polynucleotide comprising a first polynucleotide encoding the LEDGF/P75 protein or an intermediate or a fragment of said protein, a variant, a mutation thereof, further comprising a second polynucleotide which encodes at least a portion of an HIV integrase. Election of this group requires the further election of a single type of "first

polynucleotide" encoding either 1) the protein LEDGF/P75, or 2) an intermediate, 3) fragment, 4) variant, or 5) mutation of the protein, as explained below.

Group VI, claim(s) 54–56, drawn to an isolated protein complex comprising a retroviral integrase and the LEDGF/P75 protein or a fragment, a variant, or a mutation thereof. Election of this group requires the further election of a single protein complex comprising either 1) the protein LEDGF/P75, or 2) a fragment, 3) variant, or 4) mutation of the protein, as explained below.

The inventions listed as Groups I–VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of Groups I, II, and IV is a molecule which comprises a region specifically interacting with protein LEDGF/P75 or a fragment thereof or a nucleic acid encoding said protein or fragment," which is not present in any of the other groups. The special technical feature of Group III is the screening of a large number of molecules of unknown activities for interaction with LEDGF/p75 or gene thereof, which is not a feature present in any of the other groups. The special technical features of Groups V and VI are a gene fusion comprising a gene encoding LEDGF/p75 or fragment thereof and a gene encoding HIV integrase, and an isolated protein complex comrpising LEDGF/p75 or a fragment thereof, which are not found in any of the other groups.

Accordingly, unity of invention is lacking *a priori*.

The inventions listed as Groups I, II, and IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of Groups I, II, and IV is "a molecule which comprises a region specifically interacting with protein LEDGF/P75 or a fragment thereof or a nucleic acid encoding said protein or fragment." However, this cannot be the special technical feature because the element is shown in the prior art. Van Gent et al. (1991) *Nucleic Acids Res.* 19:3821–3827 teach the expression, isolation, purification, and characterization of the HIV-1 integrase protein (see report throughout, especially pp. 3822-4). The HIV-1 integrase protein is a molecule that will inherently interact with the protein LEDGF/p75, as evidenced by Cherepanov et al. (2003) *J. Biol. Chem.* 278:372–381, who teach that HIV-1 integrase specifically associates with LEDGF/p75 in human cells.

Something which is old does not become patentable upon the discovery of a new property. Furthermore, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure *at the time of invention*, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (MPEP §2112).

In the instant case, the special technical feature, HIV-1 integrase, is anticipated by the prior art, even though the prior art may not have recognized or appreciated the inherent feature(s) of the integrase, as now recited in the claim, at the time of invention.

Accordingly, Groups I, II, and IV lack unity of invention *a posteori*, because the special technical feature common to the groups is shown in the prior art.

Further Elections (Groups I–VI)

Should Applicant elect to prosecute any one of Groups I–VI, Applicant is required to further elect a single invention thereof, as follows.

Groups I–VI each comprise claims directed to a plurality of structurally and functionally distinct products and methods requiring the use of different molecules, proteins, and nucleic acids.

For example, claim 33 specifically recites and/or implicitly embraces at least eight (8) different molecular classes, including antibodies, peptides, small molecules, antisense nucleic acids, ribozymes, and siRNAs.

According to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature. For chemical alternatives, such as the claimed antibodies, peptides, small molecules, antisense nucleic acids, ribozymes, and siRNAs, the Markush group shall be regarded as being of similar nature when (A) all alternatives have a common property or activity and (B)(1) a common structure is present, i.e, a significant structure is shared by all of the alternatives or (B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to an art recognized class of compounds in the art to which the invention pertains.

In the instant case, the alternative members of the Markush-style group do not meet these criteria because they do not share a common property or activity or belong to the same art recognized class of compounds. Although the members may all contain molecules which are capable of interacting with LEDGF/p75 or its gene, the molecular classes do not share a common

core structure essential to that utility. Accordingly, unity of invention between the Markush members is lacking and each member claimed is considered to constitute a special technical feature.

Therefore, wherever applicable, as indicated in the list of groups above, Applicant is required to elect a single type of molecule, protein, nucleic acid, fragment, mutant, variant, portion therof, and so on, for prosecution on the merits with the elected group.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder

in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In

either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis V. Wollenberger whose telephone number is 571-272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LVW
December 18, 2006

SEAN McGARRY
PRIMARY EXAMINER
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